DETAILED ACTION

Receipt is acknowledged of Applicant's amendments and remarks filed 09/21/2009. The Examiner acknowledges the following:

Claims 1-14, 24, 25, have been amended.

Claims 15 and 23 have been amended.

Claims 26-41 are new.

Newly submitted claims 31-33, and 41 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: These claims do not read on the elected species. The elected medical device was a catheter.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-33, and 41 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claim 21 is previously withdrawn.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure statement has been submitted for review.

NEW REJECTIONS

In light of applicant's amendments to claims 15, and 23, the following rejections are new:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15, 18-20, 22 and 23, 30, 35, 36, 39, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by ILLNER (US 5,709,672 see PTO/SB/08).

ILLNER teaches a method of manufacturing polymeric material for a medical device comprising treating the device with gentian violet (i.e. organic dye) and/or silver nitrate (i.e. reducing agent) in an aqueous solution or alcohol solution for a time sufficient to impregnate the solution to the device then remove the device, rinse it and allow it to dry. See e.g. claims 6-10, col. 5 line 63 to col. 6 line 15 and col. 5 lines 38-39: instant claims 15, 18, 19, 22. The polymeric material is polyurethane. See e.g. claims 6-10: instant claim 20. The device is a catheter. See e.g. claim 8. ILLNER teaches a method of manufacturing a polymeric material for

a medical device. In teaching a method manufacturing a polymeric material for a medical device, this would also be disclosing a method for making a medical device. With regards to the new limitations "wherein the impregnated polymer is effective to release the organic dye into a tissue or fluid that contacts the impregnated polymer, ILLNER has taught a method of making the composition as discussed. Until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymeric material which is instantly claimed

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16, 17, 26, 27, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over ILLNER as applied to claims 15, 18-20, 22, 23, 30, 35, 36, 39 and 40 above.

ILLNER has been discussed supra.

ILLNER teaches a method of manufacturing polymeric material for a medical device comprising treating the device with gentian violet (i.e. organic dye) and/or silver nitrate (i.e. reducing agent) in an aqueous solution or alcohol solution for a time sufficient to impregnate the solution to the device then remove the device, rinse it and allow it to dry, as described above.

ILLNER does not explicitly teach an impregnation time of between one minute and 24 hours or between 60 minutes and 240 minutes.

ILLNER does teach that in certain embodiments the device is to be exposed to the gentian violet for 72 hours, however, this is one embodiment of ILLNER and does not teach away from an immersion of about 240 minutes, which the Examiner believes would still show significant impregnation of the polymeric material albeit not at the level a longer impregnation would acquire.

ILLNER does not teach that upon extended contact of the impregnated polymer with a tissue or aqueous fluid, the organic dye leaches from the impregnated polymer into the tissue or

fluid for at least two weeks, however; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymeric material which is instantly claimed. Therefore, given the method of making the polymeric material is obviated by the prior art, it would an expected property that the organic dye would have those characteristics in vivo.

ILLNER does not teach wherein the impregnated polymer is operable to release the organic dye into a tissue or aqueous fluid in contact with the impregnated polymer for at least two months. however; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymeric material which is instantly claimed. Therefore, given the method of making the polymeric material is obviated by the prior art, it would be expected that the polymeric material would release the organic dye for the claimed time frame.

Claim 23 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over by ILLNER (US 5,709,672 as applied to claims 15, 18-20, 22, 23, 30, 35, 36, 39 and 40 above, and further in view of Wu et al. US Patent 6156, 839.

ILLNER has been discussed supra. ILLNER does not disclose ferrous gluconate or ascorbic acid as the reducing agents, however Wu et al. US Patent 6,156, 839 (hereafter the '839 patent teaches Ferrous salts (i.e. ferrous gluconate) as the reducing agent (lines 10-12 column 2). It would be prima facie obvious to one of ordinary skill in the art to substitute ferrous gluconate for silver nitrate. Section 2144.06 of the MPEP states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order

to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven.

Claims 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over by ILLNER (US 5,709,672 as applied to claims 15, 18-20, 22, 23, 30, 35, 36, 39 and 40 above, and further in view of Shanbrom et al. US Patent 6,361, 786.

ILLNER has been discussed supra. ILLNER does not teach organic dye methylene blue, however, Shanbrom et al. US Patent 6,361, 786 (hereafter the '786 patent) teaches an organic polymers such as polyurethane and polycarbonate containing organic dyes such as methylene blue and gentian violet (abstract, claims 1, 9, 10). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute one known organic dye for another. Section 2144.06 of the MPEP states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15, 18, 19, 20, 22 23, 30, 34, 35, 36, 37, 38, 39, and 40, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-49 of copending Application No. 11/801616. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is

directed to both methods of manufacturing and medical devices such as catheters whereby the method comprises contacting a polymeric material with a liquid composition including a paraben and an organic dye thereby providing an impregnated polymeric material. This differs from the instant application in that the paraben is used in addition to the dye, however, both the paraben and dye are known antimicrobial agents it is It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

RESPONSE TO ARGUMENTS

Applicant's arguments with regard to the rejection of claims 1 and 3 and under 35 USC 102(b) anticipated by ILLNER (US 5,709,672 see PTO/SB/08) have been fully considered, but they are not persuasive.

Applicant alleges that Illner teaches silver nitrate, but contrary to the examiners statement that silver nitrate is a reducing agent, silver nitrate is not a reducing agent but rather an oxidizing agent.

In response the examiner respectfully submits that while it is acknowledge that silver nitrate is commonly known as an oxidizing agent, as evidenced by Wu et al. US Patent 6156,

839, silver nitrate has been known and can constitute a reducing agent (lines 10-15 column 2). Additionally, it is known that silver taken alone is a reducing agent. Silver nitrate decomposes when heated yielding silver which is a reducing agent (wikipedia-silver nitrate-reactions).

CONCLUSION

All claims have been rejected; no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DA/
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615